

**Notice of Allowability**

Application No.

09/889,936

Examiner

Nelson Yang

Applicant(s)

WILLNER ET AL.

Art Unit

1641

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/5/06.
2. ☒ The allowed claim(s) is/are 79-81 83-140, renumbered 1-61 respectively.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|   | 9. <input type="checkbox"/> Other _____   |

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Allen Yun on June 12, 2006.

2. The application has been amended as follows:

Please replace claims 79-81, 86, 90 with the following:

79. An isolated antibody or antibody fragment, comprising heavy and light chain variable region sequences of SEQ ID Nos: 6 and 8

80. The isolated antibody or antibody fragment of claim 79, which is selected from the group consisting of monoclonal antibodies, IgM antibodies, IgG antibodies, an antibody without the Fc region, and a single chain antibody.

81. The isolated antibody or antibody fragment of claim 79, [A monoclonal antibody of Claim 80] which is a monoclonal antibody [designated herein as the 5B3 monoclonal antibody].

86. An apparatus according to claim 83, wherein said first antibodies are [5B3] monoclonal antibodies.

90. An apparatus according to claim[s] 83, wherein said assay molecule is DNT or TNT.

Please amend claims 93, 98, 103, 109, 119, 124, 129, 135 as follows:

In claim 93, please delete the phrase "according to claim 91,".

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In claim 98, please delete the phrase "according to claim 91,".

In claim 103, please delete the phrase "according to claim 91,".

In claim 109, please delete the phrase "according to claim 91,".

In claim 119, please delete the phrase "according to claim 115,".

In claim 124, please delete the phrase "according to claim 115,".

In claim 129, please delete the phrase "according to claim 115,".

In claim 135, please delete the phrase "according to claim 115,".

3. The following is an examiner's statement of reasons for allowance: the prior art does not teach isolated antibody or antibody fragments comprising the sequences of SEQ ID NOs: 6 and 8, nor the use of these sequences.

4. It should be noted that since claims 79-81, which is drawn to a product, were found allowable, claims 82-140 have been rejoined, as the claims require the product of claims 79-81.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

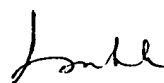
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nelson Yang  
Patent Examiner  
Art Unit 1641

  
LONG V. LE 06/12/06  
SUPERVISORY PATENT EXAMINER  
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